

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA

CLYDE W. KELLER,

Plaintiff,

v.

**COMPLAINT AND  
DEMAND FOR  
JURY TRIAL**

4:14 cv 120

AbbVie INC.; ABBOTT LABORATORIES,  
INC.; ACTAVIS, PLC; ACTAVIS, INC. F/K/A  
WATSON PHARMACEUTICALS, INC.;  
WATSON LABORATORIES, INC.,  
INDIVIDUALLY AND AS SUBSIDIARY TO  
ACTAVIS, INC.; ANDA, INC., INDIVIDUALLY  
AND AS SUBSIDIARY TO ACTAVIS, INC.;  
McKESSON CORPORATION; PFIZER, INC.  
and PHARMACIA & UPJOHN COMPANY, LLC,  
a division of Pfizer, Inc.

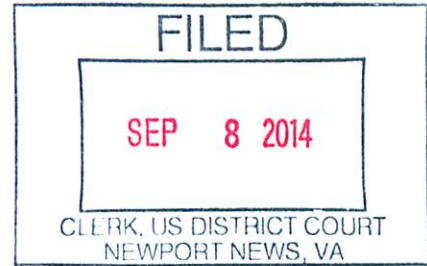
Defendants.

**COMPLAINT**

Plaintiff, Clyde W. Keller (hereinafter "Plaintiff"), by and through his undersigned counsel, H. Seward Lawlor, by way of Complaint against AbbVie, Inc., Abbott Laboratories, Inc., Actavis, PLC, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., individually and as subsidiary to Actavis, Inc., Anda, Inc., individually and as subsidiary to Actavis, Inc., McKesson Corporation, Pfizer, Inc., Pharmacia & Upjohn Company (hereinafter collectively "Defendants"), upon information and belief, allege as follows:

**INTRODUCTION**

1. This case involves the testosterone replacement therapy products Depo-Testosterone, AndroGel and Androderm, which are promoted, sold and distributed by Defendants. Depo-Testosterone is a prescription injectable



product, which is manufactured, promoted, sold and distributed by Pfizer, Inc. and Pharmacia & Upjohn Company (“Depo-Testosterone Defendants”). AndroGel is a prescription testosterone gel, which is manufactured, sold, distributed and promoted by Defendants, AbbVie, Inc. and/or Abbott Laboratories, Inc. (“AndroGel Defendants”). Androderm is a prescription testosterone patch manufactured, promoted, sold and distributed by Defendants, Actavis, PLC, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., individually and as a subsidiary to Actavis, Inc., Andia, Inc., individually and as a subsidiary to Actavis, Inc., and/or McKesson Corporation (“Androderm Defendants”).

2. For years, Defendants have claimed that Depo-Testosterone, AndroGel and Androderm are safe and effective for the treatment of hypogonadism or “low testosterone”. Despite these claims, Depo-Testosterone, AndroGel and Androderm cause serious and life-threatening medical problems, including strokes, heart attacks and thrombolytic events.

3. Defendants failed to conduct adequate pre- and post-market safety testing and research to ensure that Depo-Testosterone, AndroGel and Androderm were safe for their intended use and failed to adequately warn physicians about the risks associated with these products and the monitoring regimen required to ensure patient safety.

4. Defendants misrepresented, concealed and omitted material facts regarding the safety and efficacy of Depo-Testosterone, AndroGel and Androderm in treating hypogonadism, a condition Defendants refer to as simply “low testosterone”.

5. Depo-Testosterone, AndroGel and Androderm can cause serious injury and bodily harm. For example, Depo-Testosterone, AndroGel and Androderm cause the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored regularly and controlled properly, can lead to life-threatening heart attacks, strokes and thrombolytic events.

6. As a result of Defendants' aggressive and misleading marketing campaign, taken together with the marketing campaigns of other testosterone supplement manufacturers, medical diagnoses of "Low T" have increased exponentially. It is estimated that between 2001 and 2011, testosterone prescriptions tripled among men older than 40. Walk-in clinics have sprung up across the country and sales are expected to more than triple from \$1.6 million to \$5 billion by 2017. Yet, the New England Journal of Medicine has warned that only about 2 percent of men older than 40 should actually be receiving testosterone replacement therapy.

7. As recent safety studies demonstrate, consumers were misled as to the drugs' safety and efficacy. In fact, a study released in November 2013 of more than 8,000 men treated in the Veterans Health Administration found testosterone therapy significantly increased the risk of heart attack, stroke and death.

8. As a result of Defendants' misconduct, thousands of men, including Plaintiff, have suffered severe injuries, including but not limited to, life-threatening cardiac events, strokes and thrombotic events.

**PARTIES**

9. Plaintiff, CLYDE W. KELLER, is and was, at all times relevant herein, an adult resident of Newport News, Virginia.

10. Defendant Pfizer, Inc. is a domestic corporation, organized and existing under the laws of the state of Delaware, with its principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017. At all times relevant herein, Defendant Pfizer, Inc. was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Depo-Testosterone.

11. By way of background, in 1995, Upjohn merged with Pharmacia to form Pharmacia & Upjohn. In March 2000, the company merged with the Monsanto Company and took the name Pharmacia Corporation. Pfizer, Inc and Pharmacia began operating as a unified company on April 16, 2003. At all times relevant herein, Defendant Pfizer, Inc. was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Depo-Testosterone.

12. Defendant Pharmacia & Upjohn Company, LLC is a domestic limited liability company, organized and existing under the laws of the state of Delaware, with its principal place of business located at 7000 Portage Road Kalamazoo, MI 49001. At all times relevant herein, Defendant Pharmacia & Upjohn Company, LLC was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Depo-Testosterone.

13. Defendant AbbVie, Inc. is a domestic corporation, organized and existing under the laws of the state of Delaware, with its principal place of business located at 1 North Waukegan Road, North Chicago, Illinois 60064. At all relevant times herein, AbbVie, Inc. was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including AndroGel.

14. Defendant Abbott Laboratories, Inc. is a domestic corporation, organized and existing under the laws of the state of Illinois, with its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. At all relevant times herein, Abbott Laboratories, Inc. was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including AndroGel.

15. By way of background, Unimed Pharmaceuticals, Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals, Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division, which included AndroGel. In 2013, Abbott created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

16. Defendant Actavis, PLC is a foreign corporation, organized and existing under the laws of Ireland, with its global headquarters located at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Actavis, PLC also has administrative headquarters located at Morris Corporate Center III, 400 Interpace Parkway,

Parsippany, New Jersey 07054. At all relevant times herein, Actavis, PLC was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Androderm.

17. Defendant Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc., is a domestic corporation, organized and existing under the laws of the state of Nevada, with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. By way of background, Watson Pharmaceuticals, Inc. acquired Actavis Group in 2012 and announced shortly thereafter that as of January 2013, it would change its name to Actavis, Inc. Watson Pharmaceuticals, Inc. acquired the original manufacturer of Androderm, TheraTech, Inc., in 1999. At all relevant times herein, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Androderm.

18. Defendant Watson Laboratories, Inc. is a domestic corporation, organized and existing under the laws of the state of Nevada, with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At all times relevant herein, Defendant Watson Laboratories, Inc., a subsidiary of Actavis, PLC, was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Androderm.

19. Defendant Anda, Inc. is a domestic corporation, organized and existing under the laws of the state of Florida, with its principal place of business located at 2915 Weston Road, Weston, Florida 33331. At all times relevant herein,

Defendant Anda, Inc., a subsidiary of Actavis, PLC, was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Androderm.

20. Defendant McKesson Corporation is a domestic corporation, organized and existing under the laws of the state of Delaware, with its principal place of business located at One Post Street, San Francisco, California 94104. At all times relevant herein, Defendant McKesson Corporation was engaged in the research, development, manufacture, sales, marketing and/or distribution of pharmaceutical products, including Androderm.

### **JURISDICTION AND VENUE**

21. The jurisdiction of this Court over the subject matter of this action is predicated on 28 U.S.C. § 1332. The amount in controversy exceeds \$75,000, exclusive of interest and costs, and, because complete diversity exists between the parties, as Plaintiff is a citizen of Virginia and Defendants are incorporated in, and have their principal places of business in, states other than Virginia.

22. Venue in this Court is proper pursuant to 28 U.S.C. § 1391, in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this District.

### **GENERAL ALLEGATIONS**

23. This action is for damages brought on behalf of Plaintiff, CLYDE W. KELLER, who was prescribed and supplied with, received, taken and/or applied and/or has been injected with the prescription drugs, Depo-Testosterone, AndroGel and Androderm, as tested, studied, researched, evaluated, endorsed,

designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief, in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by these drugs.

24. Defendants' wrongful acts, omissions and fraudulent misrepresentations caused and/or were substantial factors in causing Plaintiff's injuries and damages.

25. At all times herein mentioned, Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drugs Depo-Testosterone, AndroGel and Androderm for use, injection and/or application by Plaintiff, CLYDE W. KELLER.

26. At all times herein mentioned, Defendants were authorized to do business within the Plaintiff's state of residence.

27. At all times herein mentioned, the officers and directors of Defendants participated in, authorized and directed the production and promotion of the aforementioned products when they knew, or in the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products,



thereby actively participated in the tortious conduct which resulted in the injuries and damages suffered by the Plaintiff, CLYDE W. KELLER.

28. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the cause of Plaintiff's injuries at an earlier time, and when Plaintiff's injuries were discovered, their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing his injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and the medical profession, that Depo-Testosterone, AndroGel and Androderm are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

## **OVERVIEW**

### **A. The Rise of Testosterone Therapy**

29. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or non-production of testosterone.

30. In 1999, when Unimed Pharmaceuticals, Inc., one of the AndroGel Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men".

31. In 2000, when the FDA approved AndroGel, the company announced that the market was “four to five million American men”. By 2003, that number increased to “up to 20 million men”. However, a study published in the Journal of the American Medical Association (“JAMA”) in August 2013, entitled, “Trends in Androgen Prescribing in the United States, 2001-2011”, indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before receiving a testosterone prescription.

32. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers’ offices and distributed to potential users and online media.

33. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experience any of the “symptoms” of low testosterone. These “symptoms” include listlessness, increased body fat and moodiness – all general symptoms that are often a result of aging, weight gain or lifestyle, rather than low testosterone.

34. Since the FDA approved Depo-Testosterone, AndroGel and Androderm, Defendants have sought to convince primary care physicians that

low testosterone levels are widely under-diagnosed and that conditions associated with normal aging could be caused by low testosterone levels.

35. While running their disease awareness campaign, non-injection AndroGel and Androderm Defendants promote their products as easy-to-use testosterone replacement therapies. These Defendants contrast their products' at-home application with less convenient prescription testosterone injections, which require frequent doctor visits.

36. Defendants successfully created a robust and previously non-existent market for their drugs. Defendants engaged in an aggressive direct-to-consumer and physician marketing and advertising campaign to grow the market for Depo-Testosterone, AndroGel and Androderm. For example, Androderm Defendants' website indicates that it is "For men with low testosterone", a condition which the Androderm website claims is largely caused by the aging process. The Androderm website also represents that Androderm is "highly effective" and that its design ensures proper dosing and minimizes risk.

37. In November 2013, a JAMA study was released entitled, "Association of Testosterone Therapy with Mortality, Myocardial Infarction and Stroke in Men with Low Testosterone Levels", which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

38. On January 29, 2014, a study was released in PLOS ONE entitled, "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescriptions in Men", which indicated that testosterone use doubled the risk of heart attacks in men over sixty-five years of age, as well as men younger than sixty-five with a previous diagnosis of heart disease.

**B. Depo-Testosterone**

39. The Food and Drug Administration approved Depo-Testosterone in July 1979. Depo-Testosterone is a prescription injectable product, which is manufactured, promoted, sold and distributed by Pfizer, Inc. and Pharmacia & Upjohn Company (“Depo-Testosterone Defendants”).

40. Depo-Testosterone is an intramuscular injection containing testosterone cypionate, which is the oil-soluble 17 (beta)-cyclopentylpropionate ester of the androgenic hormone testosterone, given by injection into the buttock muscle as directed by a physician, usually every 1 to 4 weeks.

41. Depo-Testosterone use produces undesirable side effects in patients who use the drug, including but not limited to, myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism and death.

42. In some patient populations, Depo-Testosterone use may increase the incidence of myocardial infarctions by over 50%.

43. Depo-Testosterone Defendants concealed relevant material information from potential Depo-Testosterone users and minimized user and prescriber concern regarding the safety of Depo-Testosterone.

44. In particular, Depo-Testosterone Defendants, in their warnings, commercials, online and print advertisements, failed to mention any potential cardiac or stroke side effects and falsely represented that Depo-Testosterone Defendants adequately tested Depo-Testosterone for all likely side effects.

45. As a result of Depo-Testosterone Defendants’ advertising, marketing and representations about its product, men in the United States pervasively sought out prescriptions for Depo-Testosterone. If Plaintiff had known the risks

and dangers associated with Depo-Testosterone, Plaintiff would not have used Depo-Testosterone and consequently, would not have been subject to its serious side effects.

**C. AndroGel**

46. AndroGel is a hydroalcoholic gel containing testosterone in either 1% or 1.62% concentrations, applied to the chest, arms or stomach, entering the body through transdermal absorption. The AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement. AndroGel is a prescription testosterone gel, which is manufactured, sold, distributed and promoted by Defendants, AbbVie, Inc. and/or Abbott Laboratories, Inc. (“AndroGel Defendants”).

47. The Food and Drug Administration approved AndroGel 1% on February 28, 2000, and AndroGel 1.62% was approved in April 2011 for the treatment of adult males who have low or no testosterone. After FDA approval, AndroGel was widely advertised and marketed by AndroGel Defendants as a safe and effective testosterone replacement therapy.

48. Defendant Abbott Laboratories spent \$80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing, including commercials and its websites, [www.IsItLowT.com](http://www.IsItLowT.com) and [www.DriveForFive.com](http://www.DriveForFive.com), sites which recommend that men have regular checkups with their physicians and five regular tests done, including: cholesterol, blood pressure, blood sugar, prostate-specific antigen and testosterone.

49. AndroGel Defendants' advertising paid off in a return of \$1.4 billion in sales during the past year, making AndroGel the biggest selling androgen drug in the United States.

50. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance Low-T. See Singer, *Selling That New-Man Feeling*, *supra*; see also Larry Dobrow, *All-Star Large Pharma Marketing Team of the Year: AndroGel*, Jan. 2, 2013, Medical Marketing & Media, available at: <http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article 273242/>.

51. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of AndroGel is safe for human use, even though AndroGel Defendants knew these to be false, and even though AndroGel Defendants had no reasonable grounds to believe them to be true.

**D. Androderm**

52. Androderm is a patch containing 2, 2.5, 4 or 5 mg. of testosterone, applied to the stomach, arms, back or thighs, and enters the body through transdermal absorption. Androderm is a prescription testosterone patch manufactured, promoted, sold and distributed by Defendants, Actavis, PLC, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., individually and as a subsidiary to Actavis, Inc., Anda, Inc., individually and as a subsidiary to Actavis, Inc., and/or McKesson Corporation ("Androderm Defendants").

53. In 1994, when TheraTech, Inc., the original manufacturer of Androderm, asked for FDA approval of Androderm, hypogonadism was considered to be a relatively uncommon condition among American men.

54. The U.S. Food and Drug Administration approved Androderm on September 29, 1995, for the treatment of adult males who have low or no testosterone. Since receiving FDA approval, the Androderm Defendants, their subsidiaries and predecessors advertised and marketed Androderm as safe and effective to treat low testosterone in men.

55. After Androderm was approved by the FDA in 1995, Androderm Defendants also engaged in a media campaign to convince men who were experiencing the typical effects of the aging process that they were suffering from low testosterone, which could be treated with Androderm. The marketing campaign consisted of advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Androderm users, and online media, including Defendants' website for Androderm, [www.myandroderm.com](http://www.myandroderm.com).

56. Myandroderm.com asserts that 4 to 5 million otherwise healthy men experience low testosterone and encourages male visitors to the site to get "a simple blood test" to determine whether they have Low-T or testosterone. The site also identifies a number of "symptoms" that it associates with low testosterone, which are symptoms that are more commonly associated with aging, weight gain and/or lifestyle.

57. As part of their marketing campaign, Androderm Defendants promoted Androderm as an easy to apply patch for testosterone replacement

therapy. Androderm Defendants contrast their product's at-home patch with other topical testosterone supplements in that the patch protects against the transfer of testosterone to others and assures proper dosing. See Androderm Patches, available at <http://www.myandroderm.com/patches.aspx#HighlyEffective> (last visited February 2014).

58. What consumers received, however, were not safe drugs, but products which cause life-threatening problems, including strokes and/or heart attacks.

**FACTUAL ALLEGATIONS (common to all defendants)**

59. Testosterone is a primary androgenic hormone responsible for normal growth development of the male sex organs and maintenance of secondary sex characteristics.

60. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

61. In men, testosterone levels normally begin to gradually decline after the age of 30.

62. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day and medications. Resultantly, many men who fall into the hypogonadal range one day may have normal testosterone levels the next day.

63. Defendants' marketing strategies beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users



from serious dangers that Defendants knew or should have known to result from use of their products.

64. Defendants successfully marketed Depo-Testosterone, AndroGel and Androderm by undertaking a “disease awareness” marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression and lethargy were actually attributable to “Low-T”.

65. Defendants’ advertising sought to create the image and belief by consumers and physicians that the use of Depo-Testosterone, AndroGel and Androderm were safe methods of alleviating their symptoms, had few side effects, and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

66. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Depo-Testosterone, AndroGel and Androderm. Defendants deceived potential users by relaying positive information through the press, including testimonials from retired professional athletes and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

67. Defendants concealed relevant material information from potential Depo-Testosterone, AndroGel and Androderm users and minimal user and prescriber concern regarding the safety of these products.

68. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represent that Defendants adequately tested Depo-Testosterone, AndroGel and Androderm for all likely side effects.

69. There have been a number of studies suggesting that testosterone in men increases the risk of undesirable side effects to patients who use the drugs, including but not limited to, myocardial infarction, stroke and death. In some patient populations, Depo-Testosterone, AndroGel and Androderm use may increase the incidence of myocardial infarctions and death by over 500%.

70. As a result of Defendants' advertising, marketing and representations about their products, men in the U.S. pervasively seek out prescriptions for Depo-Testosterone, AndroGel and Androderm. If Plaintiff in this action had known the risks and dangers associated with Depo-Testosterone, AndroGel and Androderm, Plaintiff would not have used these products and consequently would not have been subject to their serious side effects.

### **SPECIFIC FACTUAL ALLEGATIONS**

71. Plaintiff, CLYDE W. KELLER, resides in Newport News, Virginia. From 1994 until 2012, Plaintiff was prescribed and injected with Depo-Testosterone. From 2000 until 2012, Plaintiff was prescribed and used AndroGel. From 2004 until 2012, Plaintiff was prescribed and used Androderm. In January 2014, Plaintiff discontinued use of all testosterone replacement therapy products. Plaintiff was prescribed Depo-Testosterone, AndroGel and Androderm for symptoms he and his physician attributed to low testosterone.

72. On or about October 17, 2012, Plaintiff suffered a heart attack, which was caused by Plaintiff's use of Depo-Testosterone, AndroGel and Androderm, and resulted in severe physical and emotional injuries, which affected his personal and professional life.

73. Prior to using Depo-Testosterone, AndroGel and Androderm, Plaintiff had no history of heart attack.

**FIRST CAUSE OF ACTION**  
**FAILURE TO WARN**

74. Plaintiff incorporates by reference, each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

75. The Depo-Testosterone, AndroGel and Androderm manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant health risks and serious bodily harm to consumers, and Defendants failed to adequately warn consumers and/or their healthcare providers of such risks. The Depo-Testosterone, AndroGel and Androderm manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants had reason to know, knew or should have known of the risk of serious bodily harm from the use of Depo-Testosterone, AndroGel and Androderm, Defendants failed to provide adequate warning to consumers and/or their healthcare providers of the products, knowing the products could cause serious injury.

76. As a direct and proximate result of Plaintiff's reasonably anticipated use of Depo-Testosterone, AndroGel and Androderm, as designed, manufactured,

sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

**SECOND CAUSE OF ACTION**  
**NEGLIGENCE**

77. Plaintiff incorporates by reference, each of the allegations set forth in this Complaint as though fully set forth herein.

78. At all times herein mentioned, Defendants had a duty to properly research, design, formulate, compound, test, manufacture, produce, process, assemble, inspect, market, label, package, prepare for use, distribute, sell, prescribe and adequately warn of the risks and dangers of Depo-Testosterone, AndroGel and Androderm.

79. At all times herein mentioned, Defendants negligently and carelessly designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, labeled, packaged, marketed, distributed, prepared for use and sold Depo-Testosterone, AndroGel and Androderm, and failed to adequately test and warn of the risks and dangers of Depo-Testosterone, AndroGel and Androderm.

80. Despite the fact that Defendants knew or should have known that Depo-Testosterone, AndroGel and Androderm caused unreasonable and dangerous side effects, Defendants continued to market Depo-Testosterone, AndroGel and Androderm to consumers, including Plaintiff, when there were

safer alternative methods of treating loss of energy and libido, erectile dysfunction, depression, loss of muscle mass and other similar conditions.

81. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

82. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss, in which Plaintiff suffered and will continue to suffer, as described and prayed for herein.

**THIRD CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTY**

83. Plaintiff incorporates by reference, each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

84. Prior to the time that the aforementioned products were used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians, that Depo-Testosterone, AndroGel and Androderm were of merchantable quality and safe and fit for the uses for which they were intended.

85. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied on the skill, judgment and implied warranty of the Defendants in using Depo-Testosterone, AndroGel and Androderm.

86. Depo-Testosterone, AndroGel and Androderm were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that Depo-Testosterone, AndroGel and Androderm have dangerous propensities when used as intended and will and has caused severe injuries to users.

87. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**FOURTH CAUSE OF ACTION**  
**BREACH OF EXPRESS WARRANTY**

88. Plaintiff incorporates by reference, each of the allegations set forth in this Complaint as though fully set forth herein.

89. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Depo-Testosterone, AndroGel and Androderm is safe, effective, fit and proper for its intended use. Plaintiff purchased Depo-Testosterone, AndroGel and Androderm, relying upon these warranties.

90. In utilizing Depo-Testosterone, AndroGel and Androderm, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of Defendants. These warranties and representations were false in that Depo-Testosterone, AndroGel and Androderm are unsafe and unfit for their intended uses.

91. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**FIFTH CAUSE OF ACTION**  
**FRAUD**

92. Plaintiff incorporates by reference, each of the allegations set forth in this Complaint as though fully set forth herein.

93. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Depo-Testosterone, AndroGel and Androderm, and up to the present, willfully deceived Plaintiff by concealing from him, Plaintiff's physicians and the general public, the true facts concerning these products, which the Defendants had a duty to disclose.

94. At all times herein mentioned, Defendants conducted sales and marketing campaigns to promote the sale of Depo-Testosterone, AndroGel and Androderm, and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Depo-Testosterone, AndroGel and Androderm. Defendants knew that Depo-Testosterone, AndroGel and Androderm were not safe, fit and effective for human consumption, that using Depo-Testosterone, AndroGel and Androderm is hazardous to health, and that Depo-Testosterone, AndroGel and Androderm have a serious propensity to cause serious injuries to their users, including but not limited to the injuries Plaintiff suffered.

95. Defendants concealed and suppressed the true facts concerning Depo-Testosterone, AndroGel and Androderm with the intent to defraud Plaintiff, in that Defendants knew Plaintiff's physicians would not prescribe Depo-Testosterone, AndroGel and Androderm, nor would Plaintiff have used Depo-Testosterone, AndroGel and Androderm were they aware of the true facts concerning its dangers.

96. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

**SIXTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION**

97. Plaintiff incorporates by reference, each of the allegations set forth in this Complaint as though fully set forth herein.

98. From the time Depo-Testosterone, AndroGel and Androderm were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Depo-Testosterone, AndroGel and Androderm were safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Depo-Testosterone, AndroGel and Androderm, and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned products.

99. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

100. The representations by Defendants were in fact false, in that Depo-Testosterone, AndroGel and Androderm are not safe, fit and effective for human



consumption, and using Depo-Testosterone, AndroGel and Androderm has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

101. The foregoing representations by each of the Defendants were made with the intention of inducing reliance and the prescription, purchase and use of Depo-Testosterone, AndroGel and Androderm.

102. In reliance of the misrepresentations by each of the Defendants, Plaintiff was induced to purchase and use Depo-Testosterone, AndroGel and Androderm. If Plaintiff had known the true facts and facts concealed by Defendants, Plaintiff would not have used Depo-Testosterone, AndroGel and Androderm. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

103. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

#### **PUNITIVE DAMAGES ALLEGATION**

104. Plaintiff incorporates by reference, each of the allegations set forth in this Complaint as though fully set forth herein.

105. The acts, conduct and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Depo-Testosterone, AndroGel and Androderm users, and for the primary purpose of increasing Defendants' profits from the sale and distribution of Depo-Testosterone, AndroGel and Androderm. Defendants' outrageous and unconscionable conduct

warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

106. Prior to the manufacturing, sale and distribution of Depo-Testosterone, AndroGel and Androderm, Defendants knew that said medications were in a defective condition as previously described herein and knew that those who were prescribed the medications would experience and did experience severe physical, mental and emotional injuries. Further, Defendants, through their officers, directors, managers and agents, knew that the medications presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Depo-Testosterone, AndroGel and Androderm.

107. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Depo-Testosterone, AndroGel and Androderm, and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Depo-Testosterone, AndroGel and Androderm. Defendants and their agents, officers and directors, intentionally proceeded with the manufacturing, sale distribution and marketing of Depo-Testosterone, AndroGel and Androderm, knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

108. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was

carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

- A. General damages in an amount that will conform to proof at time of trial;
- B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;
- C. Loss of earnings and impaired capacity according to proof at the time of trial;
- D. Medical expenses, past and future, according to proof at the time of trial;
- E. Past and future mental and emotional distress, according to proof at the time of trial;
- F. Punitive or exemplary damages, according to proof at the time of trial;
- G. Restitution, disgorgement of profits, and other equitable relief;
- H. Injunctive relief;
- I. Attorney's fees;
- J. Costs of suit incurred herein;
- K. Pre-judgment interest as provided by law; and,
- L. Such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: September 8, 2014

Respectfully submitted,



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